K080069

FEB 13 2008

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990 and 21 CFR part 807.92.

A. 510(k) Number:
K974596

B. Purpose for the Submission:
To seek clearance for the existing DIMERTEST® product that was manufactured by AGEN Biomedical Ltd., but is now manufactured by American Diagnostica Inc. (ADI) due to the transfer of ownership of the DIMERTEST® product-line to ADI. The performance characteristics of the modified DIMERTEST® product and a summary of the modifications made to the DIMERTEST® product that had been cleared in 1988 (K882944) are described in the DIMERTEST® 510(k) submission K974596.

C. Measurand:
D-Dimer

D. Type of Test:
Latex Immuno Assay

E. Applicant:

Submitted by:
American Diagnostica Inc.
500 West Avenue
Stamford, CT 06902
Tel. 203 602-7777 Ext. 14
Fax 203 602-5553

Contact:
Leigh Ayres
Director of Regulatory Affairs and Quality Assurance
203-602-7777 x 14

Summary Prepared:
December 17, 2007

F. Proprietary and Established Name:
DIMERTEST®

G. Regulatory Information:

1. Regulation section: 864.7320

2. Classification: Class II

3. Product code: DAP

4. Panel: Hematology

H. Intended Use:

The DIMERTEST® Latex Assay is intended for the rapid qualitative or semi-quantitative evaluation of circulating derivatives of cross-linked fibrin degradation products (D-dimer) in human plasma.

I. Device Description:

The DIMERTEST® Latex Kit is a qualitative and semi-quantitative latex agglutination slide test for cross-linked fibrin degradation products in human plasma. The active ingredient in the DIMERTEST® product is the latex reagent. This reagent consists of highly specific D-dimer monoclonal antibodies attached to polystyrene latex particles. When mixed with the latex reagent, the presence of antigen (D-dimer) in a plasma sample results in agglutination of the latex particles which can be seen with the unaided eye. A semi-quantitative estimate of the D-dimer concentration can be made by preparing dilutions of a plasma sample. The concentration is determined according to a titration matrix.

Plasma from normal individuals is not expected to agglutinate DIMERTEST® Latex. Reactive fibrinolysis will be demonstrated by latex agglutination at a plasma concentration of approximately 200 ng/mL D-dimer.

J. Substantial Equivalence Information:

1. Predicate device name(s): DIMERTEST®

2. Predicate 510(k) number: K882944

3. Comparison of the Modified DIMERTEST® Kit to the Predicate DIMERTEST® Kit:

SEQ	Kit Component	Is there a difference from the Predicate DIMERTEST® kit?	Description of the Change that Was Made to the Modified DIMERTEST® Kit
1	Latex Reagent	Yes	The supplier for the latex starting material was changed, the latex reagent in the kit is now supplied with a dropper bottle, and the cut-off value was changed from 250 ng/mL to 200 ng/mL.

SEQ	Kit Component	Is there a difference from the Predicate DIMERTEST® kit?	Description of the Change that Was Made to the Modified DIMERTEST® Kit
2	Positive Control	Yes	The formulation was not changed, but the bottle in the kit is now provided with a dropper tip.
3	Negative Control	Yes	This was not provided in the predicate DIMERTEST® kit. It is a liquid formulation ready to use and it has a dropper tip.
4	Buffer Solution	No	No changes
5	Dropper Pipette	Yes	Deleted from the modified DIMERTEST® kit. No longer necessary because the latex reagent is now supplied with a dropper tip.
6	Reading Cards	Yes	Changed to a pack of 10 disposable black background cards with 8 reaction wells marked on each card.
7	Plastic Stirrers	Yes	There was a minor change to the shape of the stirrers.
8	Intended Use	No	No changes
9	Operating Principle	No	No changes
10	Capture Antibody	No	No changes
11	Assay Sample	No	No changes

K. Standard/Guidance Document Referenced (if applicable): N/A

L. Test Principle:

The assay is based on a visible agglutination that occurs when a patient plasma containing D-Dimer is mixed with latex particles coated with monoclonal antibodies.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Intra-assay (within run) reproducibility was determined by testing 10 replicates from three plasma pools that contained D-dimer titers ranging from 0 to 4. The test results for all ten replicates from each pool had the same values.

Inter-assay (run-to-run) reproducibility was determined by testing 10 plasma pools that had D-dimer titers ranging from 1 to 16. The assay values of the replicates from 10 runs of each plasma pool tested over a 28-day period did not vary by more than 1 titer.

b. Linearity/assay reportable range:

The reportable range for the semi-quantitative assay is 200 to 3,200 ng/mL D-dimer.

c. Traceability, Stability, and Expected Values:

The DIMERTEST® kit contains a positive control and a negative control.

The vial labels contain the expiration dates. Reagents are stored between 2° C and 8° C.

Normal plasma samples give negative results.

d. Analytical specificity:

The DIMERTEST® reagent showed no assay interference when plasma samples were spiked with interferents at the following concentrations:

Bilirubin 0.2 mg/dL
Lipids (triglycerides) 30 mg/dL
Hemoglobin 5.0 mg/dL
Protein (gamma globulin) 0.06 g/mL

The DIMERTEST® reagents are insensitive to rheumatoid factor.

e. Assay cut-off:

200 ng/mL D-dimer

2. Comparison studies:

a. Method Comparison of the Modified DIMERTEST® Reagent versus the Predicate DIMERTEST® Reagent:

Specificity Comparison

An in-house comparative study of 170 Blood Bank donor plasma samples from ostensibly healthy volunteers was performed. 95.3% of the normal results were negative by the modified DIMERTEST® reagent compared to 97.6% negative by the predicate DIMERTEST® reagent.

Sensitivity Comparison

145 plasmas from hospital patients who had a high probability of thrombotic conditions were analyzed in an in-house comparative study.

Clinical Cut-off Change

The new value of the diagnostic cut-off for the modified DIMERTEST® reagent was calculated to be 200 ng/mL D-dimer with the linear curve generated from the N=145 sensitivity study plasma samples. The D-dimer values that were determined with the predicate DIMERTEST® reagent were plotted as the x-axis and the D-dimer values that were determined with the modified DIMERTEST® reagent were plotted as the y-axis. With a slope of 1.19, the new cutoff was calculated to be approximately 20% less than the predicate DIMERTEST® reagent cut-off of 250 ng/mL D-dimer.

The new cut-off value was validated with an additional 373 patient plasmas that were tested by the modified DIMERTEST® reagent and also tested concurrently by the FDA cleared Dimertest Gold EIA method (K945642).

N. Conclusion

The modified DIMERTEST® product is substantially equivalent to the predicate DIMERTEST® product based on the comparison summary and the performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 13 2008

American Diagnostica, Inc.
C/O Leigh Ayres
500 West Avenue
Stamford, Connecticut 06902

Re: k080069
Trade/Device Name: Dimertest
Regulation Number: 21 CFR 864.7320
Regulation Name: Fibrinogen/Fibrin Degradation Products Assay
Regulatory Class: Class II
Product Code: DAP
Dated: December 19, 2007
Received: January 11, 2008

Dear Ms. Ayres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K080069

~~K974596~~

Device name:

DIMERTEST®

Indications for Use:

The DIMERTEST® Latex Assay is intended for the rapid qualitative or semi-quantitative evaluation of circulating derivatives of cross-linked fibrin degradation products (D-dimer) in human plasma.

Concurrence of CDRH, Office of Device Evaluation (ODE)

☑ Prescription Use (Per Title 21 CFR part 801.109) OR ☐ Over-The-Counter-Use

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K080069